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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,213

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11/27/2009

EXAMINER

KASTEN, ROBERT J

ART UNIT

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1795

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,213	<b>Applicant(s)</b> HIRATSUKA ET AL.	
	<b>Examiner</b> ROBERT KASTEN	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 14-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-13 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/2006, 01/29/2007, 06/12/2009</u> .                      | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the first non-final action on the merits.

Claims 1-32 are pending in this application. Claims 1-3 and 9-13 are examined herein.

### ***Election/Restrictions***

1. Claims 14-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/16/2009.
2. Claims 4-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/16/2009.

### ***Drawings***

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 2-4 are illegible. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Objections***

4. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both claims 2 and 3 have not been given patentable weight by the Examiner. Independent claim 1 is directed to a method of separating a substance. However, the dependent claims 2 and 3 are clearly directed to a separate method of forming a plasma-polymerized membrane. Examiner argues that specific steps directed to a method (in this case forming a membrane) cannot further limit a materially different method (in this case physically separating a substance). Dependent claims 2 and 3, therefore, cannot be given patentable weight and do not further limit the independent claim 1. Art rejections for claims 2 and 3 have been included for compact prosecution purposes.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by HJERTEN (US 4,680,201), from here on referred to as HJERTEN.

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Concerning Claim 1, HJERTEN teaches a method for separating a substance comprising the following steps:

- Adding a substance (human hemoglobin or human transferrin) to a separation medium (comprised of ampholytes (Pharmalyte), phosphoric acid and sodium hydroxide) which is retained in a substrate (glass tubes), wherein the surface of the substrate has been coated with a polymer ( $\gamma$ -methacryloxypropyltrimethoxysilane) which is inherently a membrane (col. 4, lines 50-66)
- Applying a separation pressure to the separation medium (2,000 V) (col. 4, line 60). Examiner has construed "separation pressure" to include the inherent electrophoretic separation force from an applied voltage during electrophoresis.

Concerning Claim 10, HJERTEN teaches that the substrate is made of glass (glass tubes) (col. 4, line 51).

Concerning Claim 11-12, HJERTEN teaches that the coated capillaries can be used for electrophoresis as well as isoelectric focusing (col. 2, lines 22-25).

Concerning Claim 13, HJERTEN teaches that the substance to be separated can be a protein (human hemoglobin) (col. 4, line 53).

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***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over HJERTEN in view of GIORDANO, JR et al. (US 4,784,769), from here on referred to as GIORDANO.

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Concerning Claim 2, HJERTEN teaches the use of a polymeric membrane coating (col. 2, lines 25-27) in a method of separating substances (col. 4, lines 50-66).

HJERTEN does not expressly teach that the membrane be formed using plasma-polymerization.

However, GIORDANO teaches a method for improving the separation of a substance (col. 3, lines 7-9) across a glass membrane (col. 1, lines 14-22) using a polymeric coating (col. 3, lines 12-15) fabricated by plasma polymerization (col. 2, lines 38-41).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the polymer membrane of HJERTEN by using the plasma polymerizing method of GIORDANO because plasma polymerization will provide superior polymer properties (GIORDANO, col. 3, lines 19-55).

Concerning Claim 3, HJERTEN teaches the use of a polymeric membrane coating (col. 2, lines 25-27) in a method of separating substances (col. 4, lines 50-66).

HJERTEN does not expressly teach using the claimed monomers to fabricate the polymeric membrane coating.

However, GIORDANO teaches a method for improving the separation of a substance (col. 3, lines 7-9) across a glass membrane (col. 1, lines 14-22) using a polymeric coating (col. 3, lines 12-15) fabricated by plasma polymerization (col. 2, lines 38-41), wherein the polymeric coating is made of acetonitrile monomers (col. 3, lines 19-20).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the polymer membrane of HJERTEN by using the plasma polymerizing method of GIORDANO, specifically the plasma polymerization of acetonitrile, because plasma polymerization will provide superior polymer properties (GIORDANO, col. 3, lines 19-55).

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over HJERTEN in view of TAN et al. (US 2002/0029968), from here on referred to as TAN.

Concerning Claim 9, HJERTEN teaches a method in which separation media is retained in a capillary substrate (col. 4, lines 51-66).

HJERTEN does not teach that the substrate can be a planar basal substrate.

However, TAN teaches a method for capillary electrophoresis (abstract) utilizing dynamic coating of the capillary surface using a coating polymer (abstract). The capillaries may be provided on a glass substrate or card [0023], which is necessarily a planar basal plate.

It would have been obvious to those of ordinary skill in the art to fashion the capillary substrate in HJERTEN in the planar basal plate conformation of TAN because the capillaries of TAN would be suitable and functionally identical substitutes for the capillaries of HJERTEN. Since the shape of the interior surface of the capillaries stays the same regardless of the substrate shape, attempting to coat the interior of the capillaries would yield no unpredictable results because the coating polymers would encounter identical surfaces during the coating process. Further, the fabrication of the capillaries as a tube like in HJERTEN or a channel through a plate like in TAN would



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yield no unpredictable behavior as regards coating of the capillary surfaces or performing separation in the capillaries.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT KASTEN whose telephone number is (571)270-7598. The examiner can normally be reached on Mon-Thurs, 8am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/

Supervisory Patent Examiner, Art Unit 1753

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/R. K./

Examiner, Art Unit 1795